

Remarks

Claims 1-39 were previously pending in the subject application. By this amendment, the applicants have canceled claim 1 and amended claims 2-20, 22-31, and 33, and added new claim 40. The specification has been amended to correct an undefined acronym. No new subject matter has been added by these amendments. Support for the amendments can be found throughout the subject specification including, for example, at page 28, paragraph 89. Accordingly, claims 2-40 are now before the Examiner for consideration.

Claims have been amended and cancelled herein in order to expedite prosecution by simplifying and reducing the number of issues for consideration. The applicants have also endeavored to lend greater clarity to the claimed subject matter. Accordingly, the amendments set forth herein should not be interpreted to indicate that the applicants have agreed with, or acquiesced to, the rejections set forth in the outstanding Office Action. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

As an initial matter, the applicants wish to thank the Examiner for allowing claims 35-39 in the subject application.

The drawings were objected to as being acceptable only for examination purposes. The applicants will provide formal drawings when the application is allowed.

The specification was objected to for informalities. The applicants have submitted an amended specification to address the noted informality. Reconsideration and withdrawal of this objection is respectfully requested.

Claims 1, 2, 14, 15, 18-20, 22, 23, and 25 have been rejected under 35 U.S.C. §102(b) as being anticipated by Littlejohn (U.S. Patent No. 3,649,199 A). The applicants respectfully traverse these grounds of rejection because the cited reference does not teach or suggest their claimed invention. However, as noted above, claim 1 has been canceled. Further, claims 2, 14, 15, 18-20, 22, 23, and 25 have been amended to depend from newly amended, independent claim 3, which the Examiner has indicated to be allowable when rewritten into independent form. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claims 33 and 35 have been rejected under 35 U.S.C. §102(b) as being anticipated by Gustafsson (U.S. Patent No. 5,447,165 A). The subject application discloses methods for measuring in exhaled breath endogenous compounds associated with medical conditions or diseases. Gustafsson merely teaches a method for monitoring in exhaled breath the anesthetizing agent that was used to sedate the patient (*i.e.*, nitrogen monoxide). There is nothing in Gustafsson regarding monitoring endogenous compounds associated with specific diseases or conditions. Thus, to expedite prosecution, claim 33 has been amended to clarify the classes of endogenous compounds to be identified. Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §102(b) is respectfully requested.

Claims 5-7 have been rejected under 35 U.S.C. § 103(a) as being obvious over Littlejohn (U.S. Patent No. 3,649,199 A). The applicants respectfully traverse this grounds for rejection because the cited reference does not disclose or suggest the claimed invention.

As noted in the Office Action, Littlejohn does not specifically teach delivering an agent by either intravenous delivery, parenteral delivery, sublingual delivery, transdermal delivery, *i.v.* delivery, continuous infusion, or an infusion pump. The Office Action indicates, however, that Littlejohn discloses “the anesthesiologist would administer anesthetic to the patient while monitoring the amount of anesthetic...,” which suggests one of ordinary skill in the art at the time the invention was made was delivering an agent to a patient using a specific delivery method.

Submitted herewith is a Declaration by Dr. Richard Melker under 37 C.F.R. §1.132 for the Examiner’s consideration. As indicated by Dr. Melker in the Declaration, in Littlejohn’s time in the early 1970’s, most anesthesiologists administered potent inhalation agents to render a patient unconscious. Non-inhalation anesthetic agents, as explained by Dr. Melker, “that could be used independently as the entire anesthetic...had not yet been discovered.” Dr. Melker continues with the example of propofol, an intravenous anesthetic agent that was only recently discovered and introduced for use in the 1980’s. Only since then has total intravenous anesthesia (TIVA) become a popular method for sedating patients. Thus, in view of Littlejohn, the ordinary skilled artisan at the time the subject invention was made would not have considered monitoring an anesthetic in the bloodstream, which has been delivered by either intravenous delivery, parenteral delivery, sublingual

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delivery, transdermal delivery, or *i.v.* bolus, because such delivery modes had not yet been implemented.

Furthermore, any implication that, once such delivery modes were implemented, it would have been obvious to the ordinary artisan to monitor such agents via analysis of exhaled breath cannot be considered seriously. As explained in the Melker Declaration, intravenous delivery of propofol has been in use for at least 15 years without any disclosure in the art regarding a method for monitoring the anesthetic agent via analysis of exhaled breath. The great extent of time delay, in view of the teachings of Littlejohn, is potent evidence that the claimed invention is not obvious.

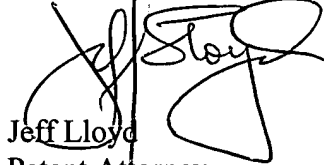
Assuming *arguendo* that Littlejohn suggests monitoring non-inhalation anesthetic agents via exhaled breath, which it does not, it is well settled that “obvious to try” is not an appropriate standard for making a *prima facie* case of obviousness. As the Examiner is undoubtedly aware, it is well established in patent law that in order to support a *prima facie* case of obviousness, a person of ordinary skill in the art must find both the suggestion of the claimed invention, and a reasonable expectation of success in making and practicing the invention, in light of the teachings of the prior art. *In re Dow Chemical Co.*, 5 U.S.P.Q. 2d 1529, 1531, (Fed. Cir. 1988). As discussed above, non-inhalation modes of delivery of anesthetic agents have been in use for at least 15 years. Within that time, there has been no disclosure in the art that monitoring such anesthetics via analysis of exhaled breath could be successful. Moreover, there is nothing in Littlejohn that provides a reasonable expectation of success in monitoring the concentration and effect of an anesthetic agent administered in a form other than via inhalation by analyzing the patient’s exhaled breath. In fact, as explained by Dr. Melker, not only has no one tried such monitoring by analysis of exhaled breath, but that “despite the popularity of TIVA, only indirect monitoring with systems that process electrical activity from the brain has been developed.” In view of the foregoing remarks and the Melker Declaration submitted herewith, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

In view of the foregoing remarks and amendment, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachments: Declaration of Richard Melker, M.D. under 37 CFR 1.132 with accompanying
curriculum vitae

